Exhibit 14

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC., AKORN, INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC.,** **Defendants.**	**Civil Action No. 2:15-cv-1455-WCB LEAD** **JURY TRIAL DEMANDED**
ALLERGAN, INC., **Plaintiff,** **v.** **INNOPHARMA, INC.,** **Defendant.**	**Civil Action No. 2:15-cv-1504-WCB**
ALLERGAN, INC., **Plaintiff,** **v.** **FAMY CARE LIMITED,** **Defendant.**	**Civil Action No. 2:16-cv-0401-WCB**

DECLARATION OF CORY J. BERKLAND, PH.D. IN SUPPORT OF PLAINTIFF ALLERGAN'S CLAIM CONSTRUCTION

I, Cory J. Berkland, Ph.D., declare as follows:

1. I am being offered as an expert to testify on behalf of Plaintiff Allergan, Inc. in support of Allergan's claim constructions on certain disputed terms in this case. I reserve the right to supplement the opinions set forth in this declaration in light of additional discovery or opinions by any expert on behalf of any Defendant in this matter. I also reserve the right to provide rebuttal opinions and testimony in response to any of Defendants' experts or any other witness for any Defendant.

I. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

2. I am currently a Professor of Pharmaceutical Chemistry and a Professor of Chemical and Petroleum Engineering at The University of Kansas. I have an appointment as a courtesy professor in the Chemistry Department. I have also assisted in designing the BioEngineering graduate program at The University of Kansas, and I am the former director of the Biomolecular Engineering track within the BioEngineering program.

3. I received a Doctor of Philosophy degree from the University of Illinois in 2003 and a Master of Science degree from the University of Illinois in 2001, both from the Department of Chemical and Biomolecular Engineering. I received a Bachelor of Science degree from Iowa State University Department of Chemical Engineering in 1998. A copy of my curriculum vitae is attached as Ex. A.

4. I have worked in the area of pharmaceutical formulation for nearly 15 years. A significant portion of my career has been dedicated to the study of engineered particles, in particular aspects relating to particle size and surface chemistry. I currently research processes for controlling the attributes of particles on the micro- and nano-scale. I have extensive experience in the area of pharmaceutical nanoparticulates and related theories, processing, formulation and analysis.

5. I have published approximately 134 peer-reviewed papers, and I have presented my research at many national and international research conferences and to companies, including more than 50 invited talks. I have given distinguished lectures such as the Nagai Foundation Distinguished Lectureship in Japan and a lectureship at the Center of Excellence in Nanotechnology at the Massachusetts Institute of Technology. I serve or have served on the editorial advisory board for a number of peer-reviewed journals: *Therapeutic Delivery*, *The Journal of Pharmaceutical Sciences*, and *The Journal of Pharmaceutical Innovation*. I also

serve on advisory boards for the Drug Discovery and Development of Experimental Therapeutics program and the National Institutes of Health Pharmaceutical Aspects of Biotechnology training grant program at The University of Kansas.

6. I have received funding for my research from the National Institutes of Health, the National Science Foundation, the Department of Defense, the Defense Threat Reduction Agency, the PhRMA Foundation, the Coulter Foundation, the American Heart Association, the Cystic Fibrosis Foundation, the Juvenile Diabetes Research Foundation, several other philanthropic organizations and multiple pharmaceutical companies.

7. I am an active participant in a number of professional societies including the American Institute of Chemical Engineers, the Controlled Release Society, the American Chemical Society, and the American Association of Pharmaceutical Scientists. I have also been elected Fellow of the American Institute for Medical and Biological Engineering.

8. I have received numerous awards in recognition of research, including the Controlled Release Society Young Investigator Award and the Coulter Translational Research Award. At The University of Kansas, I have received major research awards such as the University Scholarly Achievement Award, Jim Baxendale Commercialization Award, Leading Light Award and Miller Professional Development Award for Research, and I was named a Bellows Scholar in the School of Engineering at The University of Kansas. I have also received the W.T. Kemper Fellowship for teaching excellence at The University of Kansas.

9. I have been granted multiple patents and have co-founded three companies: Orbis Biosciences, Savara Pharmaceuticals and Orion BioScience. I have held executive positions at each of these companies. I am currently the Chief Scientific Officer, member of the Board of Directors, and Chair of the Scientific Advisory Board at Orbis Biosciences. I am also currently

the Chairman of the Board of Directors at Orion BioScience. I have worked as a consultant in the pharmaceutical industry providing formulation advice to multiple major pharmaceutical and biotechnology companies. I have also worked at one of the top three Biotechnology investment firms, Sofinnova Ventures, during a six-month sabbatical in 2014.

10. In the last four years, I have testified as an expert at trial and by deposition in the following matters: *AstraZeneca v. Apotex Corp.*, Civil Action No. 01 Civ. 9351(DLC)(S.D.N.Y); *Baxter Healthcare S.A. v. HQ Specialty Pharma Corp.*, Civil Action No. 2:13-cv-06228 (D.N.J.); *Par Pharms., Inc. v. TWi Pharms. Inc.*, Civil Action No. CCB-11-2466 (D. Md.); *Fournier Pharma Inc. v. The Minister of Health, Federal Court of Canada*, Docket: T-1184-10; *iCeutica Pty Ltd. v. Lupin Limited*, Civil Action No. 14-01515 (D. Del.).

11. I am being compensated for my time at my standard rate of $500 for each hour of service I provide in connection with this case. This compensation is not contingent upon my opinions or testimony, the outcome of this case, or any issues involved or related to this case.

II. LEGAL STANDARDS

12. In expressing opinions on what I understand might be considered to be legal issues, I have applied the following legal standards conveyed to me by Allergan's counsel.

13. I understand from Allergan's counsel that terms in patent claims must be read as they would have been understood by a person of ordinary skill in the art at the relevant time period. I have been advised by Allergan's counsel that the relevant time period is approximately September 2003.

14. I understand that, when interpreting the meaning of patent claims, it is necessary to do so in light of the intrinsic evidence, including the plain meaning of the claim terms, the

specification, and the prosecution history. When the meaning of a claim term is clear from the intrinsic evidence, there is no need for extrinsic evidence.

15. I understand that, in a patent, there may be both independent claims and dependent claims. I further understand that dependent claims must be read to contain all the limitations that are present in the independent claims from which they depend.

III. LEVEL OF ORDINARY SKILL IN THE ART

16. I understand that claims are to be interpreted from the perspective of a person of ordinary skill in the art at the time of the invention.

17. In my opinion, a person of skill in the art is a person with a scientific degree, either Ph.D., M.D., M.S., or B.S., who has at least 2-3 years of experience developing pharmaceutical formulations or treatment methods for the eye, including emulsions, or is an ophthalmologist who has 2-3 years of experience treating dry eye or keratoconjunctivitis sicca, including with emulsions, who also has assisted in developing ophthalmic pharmaceutical formulations or in designing or running clinical trials on such formulations. This person may also work in collaboration with other scientists and/or clinicians who have experience developing ophthalmic pharmaceutical formulations, developing emulsion formulations for pharmaceutical use, running clinical trials related to such formulations, and/or treating patients using such formulations. I am one of at least ordinary skill in the art in the art under that definition.

IV. BACKGROUND

18. Allergan's drug Restasis® is a therapeutic ophthalmic emulsion that delivers an active ingredient, cyclosporin[1] A, to a patient's eye using a drug-delivery vehicle comprised of

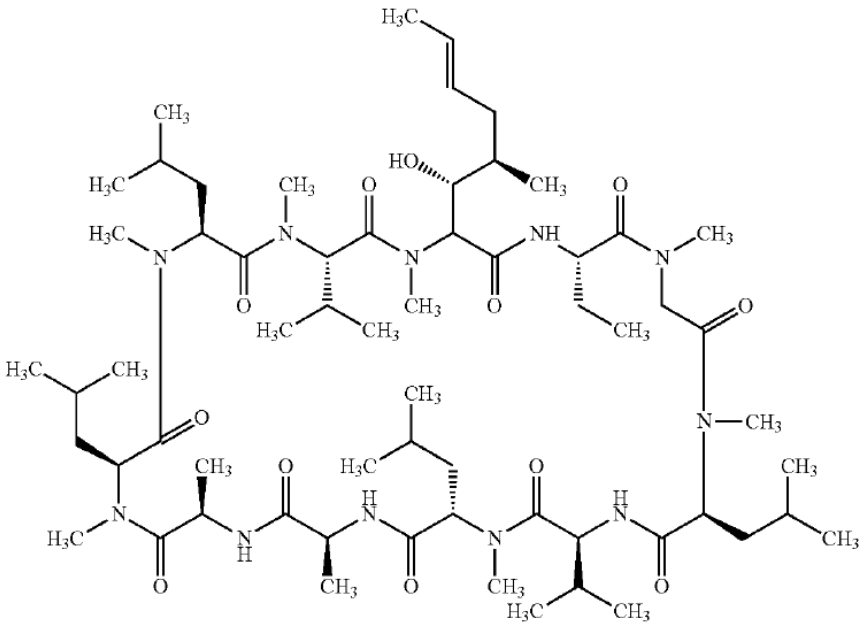
[1] "Cyclosporin" has an alternative spelling of "cyclosporine." A POSA would understand the terms can be used interchangeably.

castor oil, water, and other excipients. (Ex. B, Restasis® Label (AGN_RES0069704-AGN_RES0069709), at AGN_RES0069707.) The FDA approved indication of Restasis® is to "increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca." (Ex. B, Restasis® Label, at AGN_RES0069704.)

19. I understand that the six patents-in-suit cover Restasis®, including ophthalmic topical emulsions and methods of treatment using Restasis® to treat keratoconjunctivitis sicca. The '111 patent covers a topical ophthalmic emulsion comprising 0.05% cyclosporin A by weight, 1.25% castor oil by weight, and other excipients. (Ex. C, '111 patent, at 15:14-20.) The '111 further requires that cyclosporin A be the "only peptide present" in the claimed emulsion. (Ex. C, '111 patent, at Claim 1, 15:14-20; *see also*, Ex. C, '111 patent, at Claims 13 and 18, 15:52-16:7, 16:20-31.)

20. Cyclosporin A, the active ingredient of Restasis®, is a known immunosuppressant. (Ex. C, '111 patent, at 3:27-28.) A structure of cyclosporin A, identified as Formula 1 in the '111 patent, is included below.

Formula 1



(Ex. C, '111 patent, at 6:33-59.)

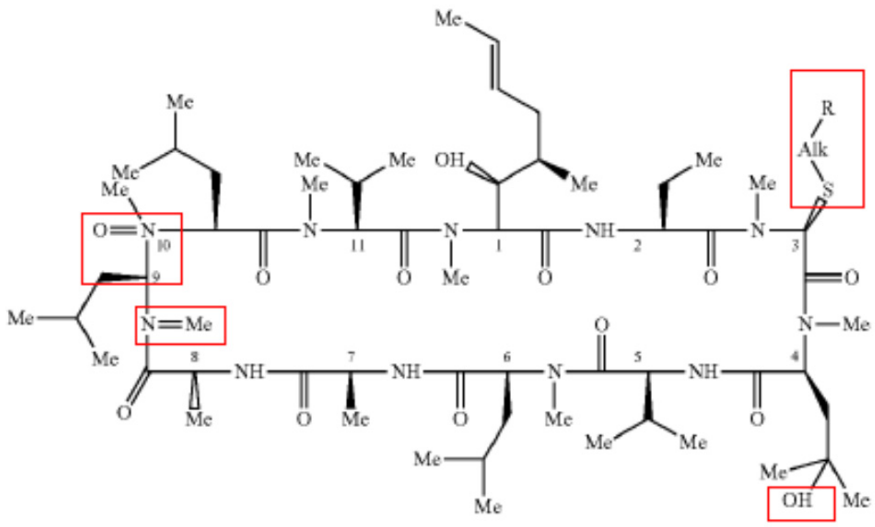
21. Cyclosporin A is part of a larger group of cyclosporins, which are nonpolar cyclic oligopeptides also with known immunosuppressant activity. (Ex. C, '111 patent, at 3:27-31.) This broader group of cyclosporins includes cyclosporin A and several cyclosporin A minor metabolites, cyclosporins B-I. (Ex. C, '111 patent, at 3:27-37.)

22. The '111 patent uses the term "cyclosporin component," defined as "include[ing] any individual member of the cyclosporin group and derivatives thereof, as well as mixtures of two or more individual cyclosporins and derivatives thereof." (Ex. C, '111 patent, at 3:38-41.) Preferred "cyclosporin components," as the '111 patent uses that term, include cyclosporin A, cyclosporin A derivatives, and mixtures thereof. (Ex. C, '111 patent, at 3:42-45.) As defined, cyclosporin A, including any derivatives thereof, are "cyclosporin components."

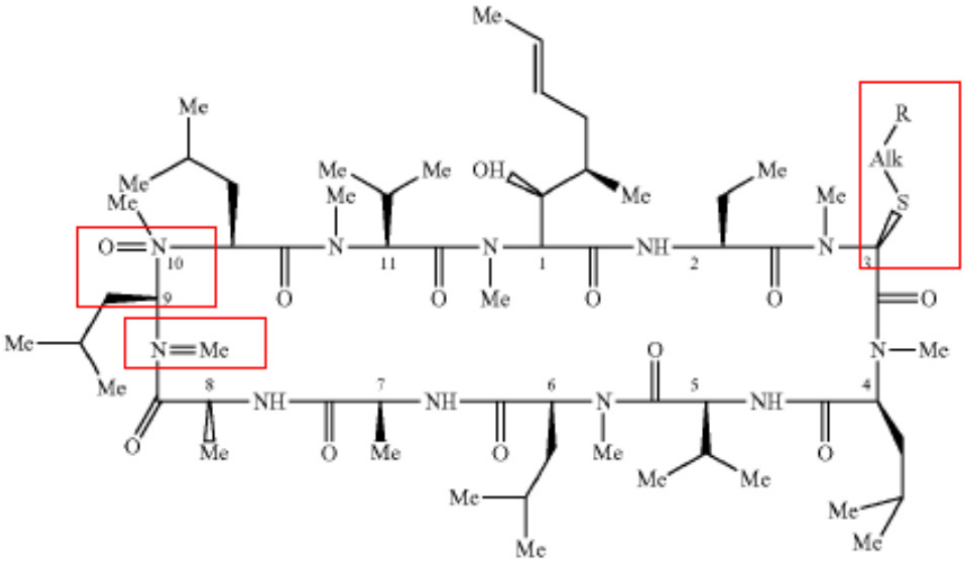
23. A "derivative" of cyclosporin, as defined in the specification, refers to "compounds having structures sufficiently similar to the cyclosporin so as to function in a manner substantially similar to or substantially identical to the cyclosporin, for example,

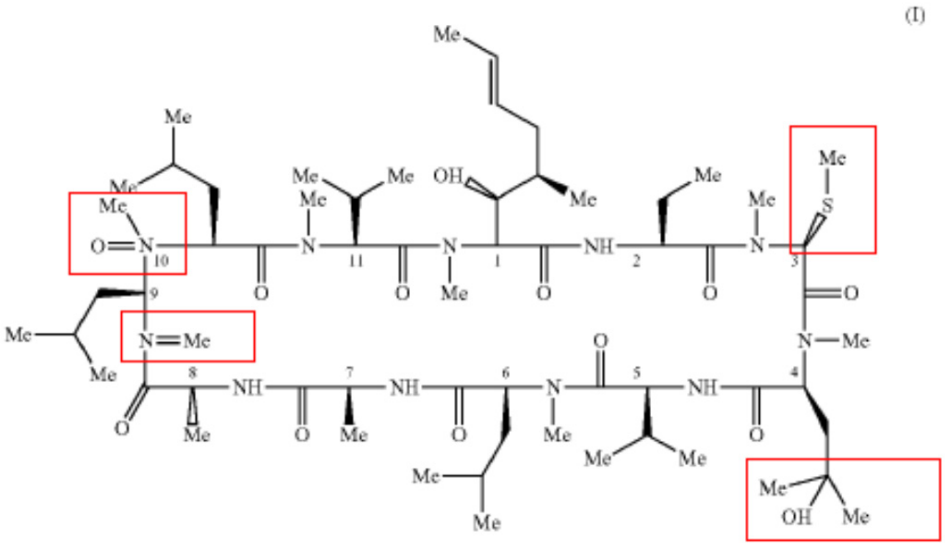
cyclosporin A, in the present methods." (Ex. C, '111 patent, at 6:59-64.) The '111 patent identifies certain cyclosporin A derivatives, including ((R)-methylthio-Sar)^3-(4'-hydroxy-MeLeu) cyclosporin A, ((R)-(Cyclo)alkylthio-Sar)^3-(4'-hydroxy-MeLeu)^4-cyclosporin A, ((R)-(Cyclo)alkylthio-Sar)^3-cyclosporin A. (Ex. C, '111 patent, at 6:59-2.) The structures of the identified cyclosporin derivatives are included below, with the differences between cyclosporin A and cyclosporin A derivatives identified in red.

(II)



(III)





(Ex. C, '111 patent, at 7:5-66, Formulas II, III, and IV respectively.)

24. As described in the specification and understood by a person of skill, a "derivative" of a compound refers to a modification to a compound that is made by a scientist at the bench. For example, and as shown above, a scientist may make a derivative of a compound by adding different chemical groups to the original compound. A "metabolite," by contrast, is created by metabolism of the compound when it is administered to an animal or a human. The specification defines cyclosporins B-I as "metabolites" of cyclosporin A.

V. OPINION ON CLAIM CONSTRUCTION

25. As defined in the '111 patent, a person of ordinary skill would understand that the phrase "cyclosporine is the only peptide present" means that cyclosporine A or its derivatives are the only peptides present in the ophthalmic emulsion. The '111 patent specification defines a "cyclosporin component" as any individual member of the cyclosporin group "and derivatives thereof." (Ex. C, '111 patent, at 38-41.) Cyclosporin A, as an individual member of the cyclosporin group, is a cyclosporin component, and, therefore, cyclosporin A or cyclosporin A derivatives are included under the definition of "cyclosporin component." The '111 patent

confirms this by identifying cyclosporin A and derivatives of cyclosporin A as "[p]articularly preferred cyclosporin components." (Ex. C, '111 patent, at 3:42-45.)

26. Based on the language of the specification, a person of ordinary skill would read the claim limitation "wherein cyclosporin A is the only peptide present in the topical ophthalmic emulsion" as including cyclosporin A and its derivatives. A person of skill would not expect that the "only peptide present" language excludes impurities.

27. The prosecution history further illustrates that the term "cyclosporin A is the only peptide present" was intended to exclude the presence of additional peptides present as ingredients in the emulsion, not merely as impurities. I understand the limitation was added to overcome a § 102 rejection over U.S. Patent 6,984,628 (the "Bakhit '628 patent"), which disclosed a formulation including TFF 3, a peptide other than cyclosporin A. (Ex. D, '111 FH, Notice of Allowability (AGN_RES0000800-AGN_RES0000812, at AGN_RES0000807.) Of particular relevance here, the TFF 3 peptide found in the alleged prior art patent was present in an amount three times greater than the cyclosporin A peptide. (Ex. E, Bakhit '628 patent (COE_JDG_PriorArt_0000841-846) at 8:20-31, Table 5). There is nothing in the intrinsic record to suggest that the term "cyclosporin A is the only peptide present" was intended to exclude impurities.

28. A person of ordinary skill would understand that natural impurities exist in every formulation. To acknowledge unavoidable impurities, industry standards exist to identify acceptable purity standpoints for chemicals.

29. The FDA recognizes that impurities exist in chemicals, and, therefore, sets accepted tolerances. As required by FDA Guidance, generic companies must identify the impurities that are present in their proposed products due to manufacturing issues or product

degradation. (Ex. F, U.S. Department of Health and Human Services Food and Drug Administration, Guidance for Industry ANDAs: Impurities in Drug Products (Nov. 2010), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatory information/guidances/ucm072861.pdf; *see also* Ex. G, Allergan NDA Excerpt (AGN_RES0004149-AGN_RES0004168).) [redacted]

30. The United States Pharmacopeia-National Formulary, which establishes reference standards for the identity, strength, and purity of medicines, identifies cyclosporine as containing no less than 97.0% and no more than 101.5% cyclosporine A. (Ex. U, USP-NF, Cyclosporine Monograph (AGN_RES1085551-AGN_RES1085552), at AGN_RES1085551.)

31. A person of ordinary skill would be familiar with such reference standards and tolerances and would understand that the language "wherein cyclosporin A is the only peptide present" naturally incorporates those accepted standards and tolerances. A person of skill would understand that the claim limitation "wherein cyclosporin A is the only peptide present" does not read out trace amounts of impurities.

VI. CONCLUSION

32. My opinions are summarized above. I may expand or modify my opinions as my investigation and study continues, and supplement my opinions in light of any relevant orders from the Court or in response to any additional information I review, any matters Defendants raise, or any opinions Defendants' experts may provide. I reserve the right to testify about these issues, should I be asked to do so, in a deposition or at trial. For testimony that I may provide in Court, at either deposition or trial, I may prepare and/or rely on demonstratives that illustrate the issues presented. I also reserve the right to respond to additional testimony from Defendants' witnesses or experts, at a hearing or at trial.

Executed this 26th day of September, 2016, at Lawrence, Kansas.

Cory J. Berkland, Ph.D.